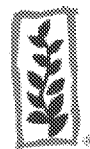


MONSANTO



**Further Discussion of Publicly Available Information
on “Incident” Inquiries**

TEST GUIDELINE

Not Applicable

STUDY COMPLETION DATE

September 7, 2018

SPONSOR/PERFORMING TESTING FACILITY

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

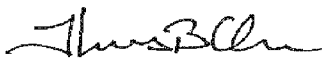
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Company: _____ Monsanto Company _____

Company Agent: _____ Thomas B. Orr _____

Title: _____ Regulatory Affairs Manager _____

Signature: _____  _____

Date: _____ 9/7/2018 _____

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This report does not meet the requirements of the Good Laboratory Practice (GLP) standards as specified in 40 CFR Part 160 as it is not a study *per se* but an assessment of data from other studies and reports.

A handwritten signature in black ink, appearing to read 'Thos B Orr', with a stylized, cursive script.

Thomas B. Orr
Regulatory Affairs Manager
Monsanto Company

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Further Discussion of Publicly Available Information on “Incident” Inquiries

On August 3, 2018, Monsanto submitted to EPA numerous new field trials and studies, along with appropriate modeling, demonstrating why, as a matter of hard science, EPA should have confidence that the Xtendimax label contains conditions for use, that when followed, are effective to prevent off-target movement “at unacceptable frequencies or levels.” In addition to those scientific evaluations, the submission also described Monsanto’s on-site evaluations of 450 alleged instances of off-target movement, confirming again through in-depth expert review of each such instance that there is no basis to conclude that the underlying scientific conclusions in the many scientific submissions were incorrect, or that label conditions are insufficient to address the potential for “off-target movement.”¹

Lacking a detailed knowledge of the substantial body of scientific studies presented to EPA, certain observers have speculated publicly that reported allegations of off-target movement in certain states may signal a reason for concern about volatility of Xtendimax, or of other dicamba herbicides currently on the market. Indeed, numerous plaintiffs firms have been using these allegations about off-target movement to actively seek plaintiffs to participate in their class action lawsuits.²

Monsanto is aware of two public sources compiling incident inquiry information (the “Compilations”): (1) incident data reported by states to the Association of American Pesticide Control Officials (AAPCO); and (2) an informal survey and compilation of estimates from university weed scientists.³ It does not appear that the information in either compilation resulted from a detailed on-site analyses or investigation (although the states may have conducted some such inquiries on some of the incidents reported). It does not appear that there was a direct examination of the actual fields underlying the inquiry, or a direct assessment of the potential source or causes of reported symptomology, or direct assessment and confirmation that reported symptomology was

¹ See “The Scientific Basis for Understanding the Off-Target Movement Potential of Xtendimax,” MRID 50642701 (August 3, 2018) (hereinafter “Off-Target Movement Paper”).

² See, e.g., Weitz & Luxenberg, “Weitz & Luxenberg Taking on Monsanto in Dicamba Lawsuits,” (available at <https://www.weitzlux.com/environmental-pollution/dicamba-litigation/>) (“Complaints against the toxic, volatile herbicide dicamba are on the rise...Already, our dicamba attorneys have been hard at work investigating numerous complaints from farmers involving the weed killer dicamba. Millions of acres have been damaged.”); Gray, Ritter & Graham, “GRG Accepting Farmer’s Dicamba Damage Cases,” (available at <https://www.grgpc.com/grg-accepting-farmers-dicamba-damage-cases/>) (“Farmers, have you suffered dicamba-related damage? Gray, Ritter & Graham, P.C., a firm with a proven history of representing farmers economically hurt through the actions of others, is here to help....Nationally, approximately 2,200 dicamba-related injury investigations have been or are being conducted with more than 3.6 million acres of soybeans demonstrating signs of dicamba damage.”); Levin Papantonio, “The Dicamba Drift Crop Damage Lawsuits,” (available at <https://www.levinlaw.com/dicamba-drift-crop-damage-lawsuit>) (same).

³ Monsanto has also reviewed the agricultural and pesticide regulatory websites for states where Xtend is approved; although many of those websites include a form where growers can report a dicamba complaint, we did not locate any state websites other than North Dakota that identified the number of dicamba complaints in 2018, alleged impacted acreage or other supporting information.

consistent with dicamba exposure, or dicamba exposure alone, rather than the myriad of other potential causes of the reported symptomology. It also does not appear that the compiled information reports whether any of the alleged incidents actually resulted in impacts on crop yield or other harm. For one of the sources, the persons compiling this information acknowledge that the information was “anecdotal,” the product of generalized “estimates” from informal telephone surveys and provided no indication the information was gathered through any rigorous scientific process. Thus, it is very important to understand the inherent limitations of such data when evaluating the entire record.

1. *No Inference Of Any Crop “Injury” Can Be Associated with the Compilations*

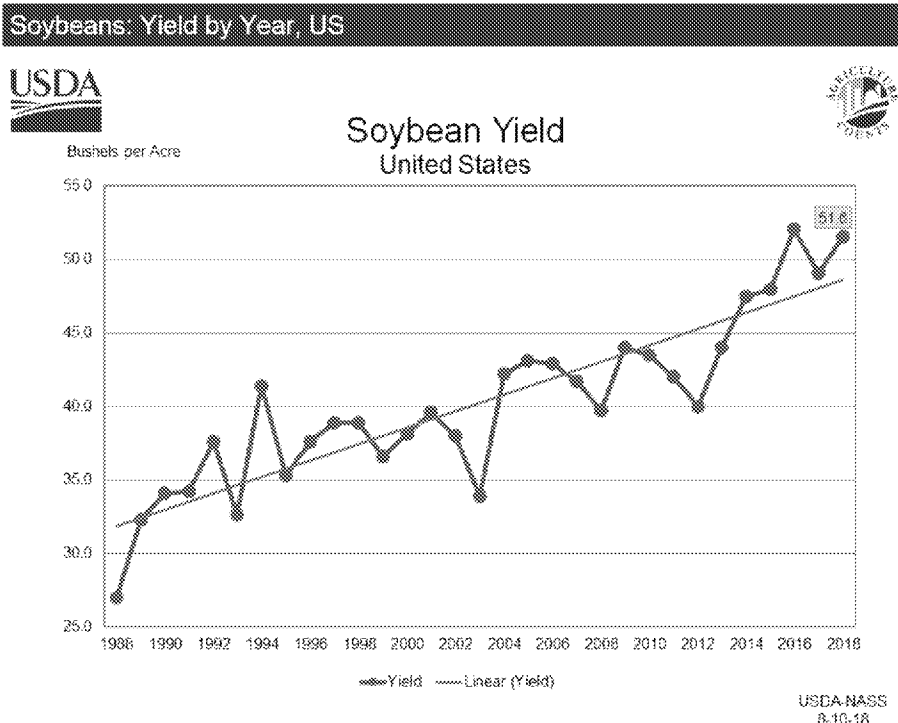
As a threshold matter, the Compilations cannot be used to predict any widespread crop injury in any location. As discussed in Monsanto’s August 3, 2018 submission, total U.S. production of soybeans hit record high levels in 2017 notwithstanding a “punishing drought” that plagued the Northern Plains from May through the remainder of the year and “erratic rainfall” that depressed other Midwestern soybean yields.⁴ Indeed, 2017 nationwide average soybean yield per acre hit the highest levels of any year in history, with the exception of 2016. Moreover, the available data suggests that in 2017, the highest yield gains occurred in many of the locations from which the highest number of complaints arose. (Lower yields were generally associated with the states and counties experiencing the extreme drought conditions; these were also areas with relatively few complaints about potential off-target movement.) As such, complaints in 2017 about alleged dicamba off-target movement cannot be associated with any widespread yield losses.⁵

In addition, USDA’s recent projections regarding 2018 yield similarly indicate no evidence of widespread crop injury from off-target movement. Indeed, USDA projects that nationwide, soybean yields per acre will increase by 5 percent as compared to 2017, reaching levels that are just barely below 2016⁶:

⁴ See “Off-Target Movement Paper,” pp. 26-31.

⁵ *Id.*

⁶ See USDA National Agricultural Statistics Survey, “Soybeans: Yield by Year, US,” available at https://www.nass.usda.gov/Charts_and_Maps/Field_Crops/soyvld.php.



Those nationwide yield projections follow from USDA’s projections of state-specific increases in yield per acre in Alabama, Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Wisconsin. Many of these states were negatively impacted by weather last year (i.e., Illinois, Iowa, Kansas, North and South Dakota, and Nebraska along with Wisconsin, Michigan, Ohio, Indiana and Minnesota).⁷ Thus, as in 2017, 2018 complaints about alleged dicamba off-target movement do not appear to be associated with any widespread yield losses.

2. *The Compilations Lack Sufficient Detail To Support Regulatory Decision-making*

As discussed in Monsanto’s August 3, 2018 submissions, Monsanto in 2018 implemented a detailed process for evaluating inquiries into off target movement, whether reported by herbicide applicators or by non-applicators. Monsanto’s Field Engagement Specialists objectively evaluated every inquiry reported to us, an evaluation that most critically included a visit to every field or site

⁷ Missouri is projected to experience an 8 percent loss in yield in 2018 owing to a debilitating drought – ranked as “exceptional drought” (the most extreme) by U.S. Drought Monitor – that has prompted USDA to offer millions in grant assistance money to Missouri farmers and ranchers. “Extreme” conditions currently cover 19 percent of the state, while “severe drought” currently impacts 43 percent of the state. See AgWeb, “Some Missouri Fields Revealing Single Digit Yields Due to Drought” (August 10, 2018) (available at <https://www.agweb.com/article/some-missouri-fields-revealing-single-digit-yields-due-to-drought/>). Arkansas similarly is experiencing a drought (with over 60% of Arkansas was in moderate drought and 89% was abnormally dry), and USDA is predicting a 2 percent yield loss there. See U.S. Drought Monitor (available at <https://www.drought.gov/drought/states/arkansas>).

allegedly affected as soon as possible after reporting of an incident, with the goal of visiting sites within three business days after a return call is received. For incidents reported by non-applicators, the Field Engagement Specialists assessed the allegedly-injured field to identify symptomology and impacted crops. All relevant facts were documented, including a precise measure of potentially impacted fields. Expert panels, independent from the Field Engagement Specialists, reviewed and evaluated all of the facts collected through this process. The data then were inputted and mapped in a database with a summary of conclusions obtained from the field inquiry.⁸

The results of Monsanto's research demonstrate why this type of detailed, site-specific inquiry is critical. For example, in a number of cases the Field Engagement Specialists were unable to identify any symptomology in the fields allegedly damaged; in others, only a very small fraction of the field exhibited any symptoms at all (*e.g.*, 0.6 acres of a 146 acre field showed minor leaf cupping). Overall, Monsanto found that the number of acres with potential symptomology of some type was low – only about 14,345 acres.⁹ These site-specific inquiries were critical for obtaining sufficient data to determine *whether* any symptomology was consistent with dicamba exposure, whether that exposure could have been caused by Xtendimax and, if so, *why* the Xtendimax application potentially caused that symptomology – which in turn enables Monsanto and EPA to evaluate what, if any, label amplifications would be most efficacious in preventing such incidents in the future.

At the beginning of the 2018 growing season, AAPCO instituted a dicamba survey where it asks state pesticide officials to report regularly on drift incidents reported to the state as of that date in 2018. Although we are confident the AAPCO data are an accurate reflection of what the states have provided to AAPCO, unfortunately it simply is not complete or consistent enough to draw any reliable conclusions. As indicated, it does not appear to reflect an investigative analysis, conclusions based on direct examination of subject fields, and contains no indication of what symptomology was observed by a state official (if any) and what the causes were, and whether any yield impact resulted.

Moreover, some states (including Kansas) elected not to participate in the AAPCO survey, while others (including Arizona, Georgia, Kentucky, Oklahoma, Tennessee and Texas) responded inconsistently. While many states reported the total number of complaints, the number of auxin complaints and the number of dicamba complaints, fewer reported the alleged acreage showing symptomology – and none provide the kind of detail reflective of an in-depth investigation. Thus, for example, where a state reports a specific amount of acreage, it is unclear whether that report is an estimate of the total size of the field, an estimate of that portion of the field that the caller believed showed symptomology, or an actual measurement performed by a state official of either. As noted above, Monsanto's site investigations found that in some cases where a complaint was lodged, there was no visible symptomology; in others, the cause was not dicamba or was likely the more volatile dicamba formulations that are permitted to be used on corn, small grains and pastures without Xtendimax's strict label conditions. Without such a thorough on-site investigation, one cannot determine whether offsite incidents are occurring at unacceptable frequencies or levels.

Likewise, the Compilation of estimates from university weed scientists lacks sufficient information to support regulatory decision making. That Compilation contains a listing of "official

⁸ See "Off-Target Movement Paper," pp. 31-45.

⁹ Additional detail on the results of Monsanto's site-specific investigations can be found in Monsanto's "Off-Target Movement Paper," pp. 31-45.

dicamba-related injury investigations as reported by State Department of Agriculture,” as well as “estimates of dicamba-injured soybean acreage in the U.S. as reported by University Weed Scientists.”¹⁰ In general, the number of investigations cited in this compilation are consistent with the numbers reported by AAPCO (although the compilation identifies numbers in several states that are not reported in the AAPCO database). The compiled estimates of the number of impacted acres, however, are wildly inconsistent with what is reported to AAPCO and with what Monsanto has documented through its detailed investigations. For example, the compilation reports that 25,000 acres were injured in Nebraska, but Nebraska itself reported only 8,500 acres with symptomology of some kind to AAPCO as of the same date; similarly, the compilation reports that 500,000 acres were injured in Illinois, but Illinois reported only 5,000 acres to AAPCO. This is a one hundred-fold difference!

Importantly, these compiled figures are “**estimates** of dicamba-injured soybean acreage from university weed scientists” – and include no information on *how* those estimates are determined, nor even any assurances that the estimates involved an actual examination of the fields at issue. At a minimum, it appears that the estimates assume that in each instance the entire field was damaged even if, in fact, only a very small fraction of the field exhibited any symptoms at all, such as the case described above where Monsanto’s investigation revealed that only 0.6 acres of a 146 acre field showed minor leaf cupping. Moreover, there is no indication that any thorough on-site investigations were conducted to assess whether the cause of symptomology was dicamba, XtendiMax, other pesticides, environmental stress, or whether dicamba applications in nearby corn, small grain or pasture resulted in the alleged symptomology.¹¹ Thus, this compilation also simply does not provide enough data to allow a determination of whether offsite incidents are occurring at unacceptable frequencies or levels.

In any event, of the alleged 1.1 million acres of dicamba-injured soybeans, the compilation reports that 400,000 acres (36%) is in Arkansas – *where all dicamba has been banned since before the 2018 growing season* (and where Xtendimax has never been sold). When considering whether to reregister XtendiMax, EPA should not give any weight to incidents in a state where use of the active ingredient has been banned, and where the product at issue (Xtendimax) has never been sold. The university weed scientist compilation also suggests that 500,000 acres of damage occurred in Illinois, where Monsanto’s research has documented that many (if not most) of the allegedly damaged fields were adjacent, nearby or surrounded by more acres of corn than of Xtend soy – such that, while dicamba might have had some role in symptomology, the dicamba at issue was higher volatility dicamba with none of the use restrictions on Xtendimax that were designed to limit off-target movement. Between them, these two states account for 82% of all of the damage alleged by in the compilation.

¹⁰ See University of Missouri Integrated Pest Management, “July 15 Dicamba injury update. Different Year, same questions,” available at <https://ipm.missouri.edu/ipcm/2018/7/July-15-Dicamba-injury-update-different-year-same-questions/> (last visited August 10, 2018).

¹¹ It is possible that some investigations have been conducted by the university weed scientists, but the results of those investigations are not reported at all in the compilation.

3. *To the Extent The Compilations Are Usable, They Demonstrate A Trend Of Reduced Complaints From 2017-2018 As Improved Applicator Training Was Implemented, Which Is Consistent With Other Sources Of Information*

Finally, even if EPA were to credit the compilation's estimates, that data supports the effectiveness of the label amplifications made for the 2018 grower season. A comparison of the AAPCO and university weed scientist acreage estimates and complaint documentation from 2017 with the latest 2018 estimates shows significant reductions in the number of impacted acres and the number of complaints in the 2018 growing season.¹² For example,

Minnesota saw a 96% reduction in complaints and a 99% reduction in impacted acres;

South Dakota saw a 86% reduction in complaints and a 96% reduction in impacted acres;

Tennessee saw a 93% reduction in impacted acres;

North Dakota saw a 92% reduction in impacted acres;

Kentucky saw a 88% reduction in impacted acres;

Kansas saw a 75% reduction in impacted acres;

Missouri saw a 56% reduction in complaints and a 69% reduction in impacted acres;

Nebraska saw a 32% reduction in complaints and a 50% reduction in impacted acres;

North Carolina saw a 53% reduction in complaints;

Indiana saw a 45% reduction in complaints and impacted acres;

Alabama saw a 43% reduction in complaints; and

Mississippi saw a 42% reduction in complaints.

A comparison of the AAPCO complaint documentation from 2017 with the latest 2018 estimates similarly shows significant reductions in the number of complaints in the 2018 growing season. For example,

Tennessee saw a 61% reduction in complaints;

South Dakota saw a 52% reduction in complaints;

Indiana saw a 45% reduction in complaints;

¹² Monsanto recognizes that this is somewhat of an apples-to-oranges comparison, as the 2017 numbers were generated in August or later; nonetheless, it is the best data we have available for comparison and subsequent reports are unlikely to result in significant changes to the 2018 numbers.

Alabama saw a 45% reduction in complaints; and
North Carolina saw a 33% reduction in complaints;
Kentucky saw a 29% reduction in complaints; and
Mississippi saw a 24% reduction in complaints.

These numbers underscore the effectiveness of the label amplifications imposed in 2018. And although Illinois reported what appears to be a 43% increase in complaints (and was the driver behind what some have claimed is an increase in incidents in 2018), that increase was the result of a changed reporting methodology between 2017 and 2018. Specifically, Illinois reported individual calls in 2017, and the number of fields allegedly impacted in 2018. So, for example, if one grower called and reported alleged impacts on 20 fields, Illinois would have recorded that as one incident in 2017 and 20 incidents in 2018.

In conclusion, the most scientifically reliable data that is currently available for assessing whether “offsite incidents are ... occurring at unacceptable frequencies or levels” are detailed, site-specific evaluations such as those conducted by Monsanto. These assessments amply demonstrate that merely counting the number of inquiries alleging impacts from the off-target movement of XtendiMax provides no reliable indication of whether there was any “incident.” Further, it is impossible to use such tallies to draw any valid conclusion about what actually occurred on a subject field. The available evidence further supports the conclusion that the recent label amplifications have made a demonstrable impact in preventing off-target movement of dicamba. But it is still important to recognize that even where a field exhibits symptomology consistent with dicamba exposure, that symptomology by itself does not indicate XtendiMax was the cause, or mean that there will be an impact on plant height or yield – and thus symptomology by itself is not necessarily relevant to EPA’s risk assessment.